

### **REMARKS/ARGUMENTS**

Claims 1, 3-5, 7-35 and 37-42 are pending in this application. The claims are all rejected under 35 U.S.C. §103.

Submitted with this Response is a declaration under 37 C.F.R. §1.132 of Dr. Jörg Kowalczyk, one of the named co-inventors of the application, in traversal of the §103 rejection noted above. Also filed with this Response is a Request for Continued Examination which is being submitted for the purpose of obtaining entry and consideration by the Examiner of Dr. Kowalczyk's evidentiary declaration. Reconsideration of the application is respectfully requested.

#### **Claim Rejection Under 35 U.S.C. §103**

In ¶3 on p. 2 of the Office Action, claims 1, 3-5, 7-32, 34, 35 and 37-42 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Kropf et al. DE 10063945 A1 (hereinafter "Kropf") in view of Greenberg et al. U.S. Patent No. 5,980,955 (hereinafter "Greenberg"). The rejection is respectfully traversed.

Both the Kropf and the Greenberg references, including the features which are believed to distinguish the presently claimed article/composition and method over the combination of those references, are extensively discussed in applicants' prior responses filed on September 22, 2008; January 30, 2009 and October 20, 2009. Those prior remarks/arguments are expressly incorporated by reference into the present discussion.

The claims pending in this application are primarily directed to a coated chewing gum and to a method for producing the chewing gum. They encompass, as well, methods for improving dental hygiene in a subject, mineralizing the tooth enamel of a subject and mineralizing the dentine of a subject, said methods requiring that the claimed coated gum is chewed by such subject. As indicated in ¶6 of the accompanying Kowalczyk declaration ("the declaration") the process for coating the chewing gum is a complex process largely dependent upon empirical observations and experience of the one carrying out the coating operation. This is mostly due to features such as unpredictable interactions between the substances used as the primary coating material, the level of solids in the coating syrup, the presence or absence of other

substances in the coating syrup, the coating conditions and the coating apparatus. Changing any of the ingredients and/or the temperatures or other reaction conditions while still producing an acceptable coating may lead to significant changes in coatings thus produced.

The Greenberg reference, as noted in ¶7 of the accompanying declaration, discloses coated chewing gum products. The coating comprises, inter alia, a small quantity of a food-acceptable poorly water-soluble calcium salt added for purposes of improving the smoothness of the finished coating. This provides an improved appearance to the finished product (see col. 1, first and second paragraphs). Further according to declaration ¶7, at col. 2, last paragraph, the Greenberg reference discloses that the calcium salts used in the coating have a solubility of about 5 g/l in water at 10°C.

The declaration goes on to indicate in ¶8 that at the temperatures conventionally used for coating chewing gums, as disclosed in Greenberg (see, e.g., Examples 2 and 3) the calcium salts are completely or, at a minimum, almost completely dissolved. The calcium salts serve as seed crystals during coating, i.e., during successive application of the coating layers and the subsequent drying of such coating layers by water evaporation. Col. 8 lines 20-25 of Greenberg disclose a syrup temperature of 85°C and intermittent drying periods.

As explained in declaration ¶9, during the drying process the moisture content of the applied coating medium that sticks to the chewing gum core is successively reduced. Additionally, the components of such coating medium, in particular the calcium salts and xylitol, successively crystallize out - thereby forming the desired crystalline coating layer. Such a coating system requires re-crystallization and at least partial solubility of the coating material, i.e., calcium salts, within the coating medium. Only under such circumstances may the calcium salts be applied to a chewing gum core in a completely or partially dissolved form to permit them to crystallize out during the drying step(s). This, thus, results in a smooth coating having an even distribution of coating material. Greenberg evidences that the process described by the patentees relies mainly on the solubility of the calcium salts used in forming the coating medium and the expected re-crystallization behavior of these salts in order to ensure precipitation at the correct time and in the proper quantity to promote proper crystallization of at least a substantial portion of the coating material contained in the coating medium.

In contrast to what is disclosed in Greenberg, as discussed in declaration ¶10 the Kropf reference does not relate to a chewing gum coating process. Rather, Kropf is directed to adhesive dental films wherein the films are prepared by adding different poorly soluble calcium salts into a solution of a water soluble or swellable polymeric carrier material and subsequently drying the resultant dispersion to obtain the resultant film. The calcium salt used in forming the subject film has a solubility of less than 1 g/l in water at 20°C which, when compared to the solubility of the calcium salt as taught in Greenberg (i.e., 5 g/l in water at 10°C) represents more than a five-fold difference in solubility. Furthermore, as also noted in declaration ¶8, taking into account that the solubilities in Greenberg and Kropf are measured at different temperatures (see above) and, furthermore, that it is well known that solubility mostly increases dramatically as the temperature is raised, the difference in the solubilities between Kropf and Greenberg are, in fact, even larger than the factor of 5 mentioned above.

The declarant then further states in ¶11 that due to the extremely low solubility of the calcium salts disclosed in Kropf, one of at least ordinary skill in this art would not regard these salts to be suitable for functioning as seed crystals in a chewing gum coating process. They would have expected that the calcium salts disclosed in Kropf would not dissolve sufficiently in a coating medium and thus would not be suitable for application in at least a partially dissolved form in a coating medium on a chewing gum core.

As pointed out in declaration ¶12, the Greenberg reference demonstrates that not every calcium salt may be used in the coating process described by the reference. The reference teaches that only the specific poorly water-soluble salts disclosed therein actually meet the requirements for forming an acceptable coating and are thus suitable for use in the described coating process. The declarant thus has determined that one, such as himself, having at least an ordinary level of skill in this art, would have no reasonable expectation of success in considering whether the calcium salts taught for use in the Kropf reference (which are much less soluble than the salts disclosed in Greenberg), could be successfully used in a coating process according to Greenberg.

As set forth in ¶13 of the declaration, both the composition of applicants' claimed chewing gum coating layer and the claimed method of preparing the coating and applying it to

the chewing gum center are entirely distinguishable over the preparation of a dental adhesive film according to Kropf. The dental film is prepared by mixing a polymer component with the calcium salt in an alcoholic solution and the mixture is subsequently dried to obtain the film. The coating layer of a chewing gum as presently claimed, however, does not employ an alcoholic solution, nor does it employ calcium salt-containing water-soluble or swellable polymer components. Furthermore, it is not obtained via a single simple drying step. The preparation and application of the coating layer, as claimed in the present application, in contrast to the disclosure contained in Kropf, involves a complex preparation process, according to which components able to form a crystal layer on a chewing gum core, under controlled agitation, are applied in a liquid form to the core and then dried. This cycle is then repeated several times as necessary.

Kropf employs, per the discussion contained in declaration ¶14, extremely poorly soluble calcium salts in a relatively technically simple system that does not require controlled crystallization of any of the coating components, in particular carbohydrates. Greenberg, however, in contrast, does employ a system that requires controlled re-crystallization of carbohydrates from a coating syrup onto the core of a chewing gum in order to form a smooth coating layer. One having at least an ordinary level of skill in the relevant art would thus not have considered the extremely poorly soluble calcium salts, i.e., of Kropf, to be applicable in the coating process of Greenberg, i.e., requiring re-crystallization.

Another factor distinguishing the presently claimed coating layer, as discussed in declaration ¶15, is that the coating recited in the present claims is comprised of calcium salt/protein composites. An artisan of at least ordinary skill in this field typically would not have considered using such a protein component with a calcium salt in a chewing gum coating process due to the fact that such protein components are known to soak up water and, thus, are very likely to negatively affect the crystallization of a carbohydrate, while additionally causing problems due to a significantly reduced solubility and a likelihood to agglomerate. Such agglomeration would be expected to result in an undesirable sticking together of the coating components, and/or the adherence of the coating components to the coating drum or the nozzle of the coating device. The deficiencies noted above, therefore, have led to the establishment of a strong prejudice in this

field of art against the use of a calcium/protein component in a process requiring the re-crystallization of carbohydrates, i.e., particularly in the coating of chewing gum cores.

The Kropf reference (see, e.g., paragraph [0003]), as mentioned by the Examiner, describes lozenges and chewing gums as constituting suitable carriers for introducing certain active components onto the tooth surface (see, e.g., declaration ¶16). This is because such carriers have a relatively long residence time in the mouth. However, Kropf fails to mention that the calcium salts recited in present claim 1, or even that calcium salt/protein composites, would be suitable for use in chewing gums. That is, only dental adhesive films are identified as suitable carriers.

As further discussed in declaration ¶17, Dr. Kowalczyk argues that even if the reference to chewing gum preparations in Kropf were somehow linked to the specific calcium salts recited in the claims of the present application, or even to the use of calcium salt/protein composites (which, as noted in the paragraph above, they are not), such combination still would not teach, or even suggest, the composition and method as recited in the claims of the present application. The general disclosure in Kropf pointing to the use of chewing gums for providing effective agents to the surface of a subject's teeth does not teach or suggest to use coatings upon the surface of such chewing gum(s) to accomplish the desired end. The coating of a chewing gum typically has an entirely different composition than that of the chewing gum core. That is, a chewing gum core consists mainly of a chewing gum base having a flexible matrix-like structure. The enveloping coating, on the other hand, does not comprise a chewing gum base. In contrast, it is comprised of a formulation designed to be readily dissolvable in water for facilitating the release of sweetness, aroma and other ingredients. Thus, the requirements for a substance to be embedded in a chewing gum core are entirely different than for ingredients used in the coating. In light of these considerations, even if the declarant, as one having at least ordinary skill in this field, had considered the general disclosure in Kropf relating to chewing gums in general as a motivating factor in suggesting the use of the calcium compositions also disclosed in Kropf in chewing gums, the suggestion would have involved including the calcium composites in the chewing gum core and not in the coating of the chewing gum.

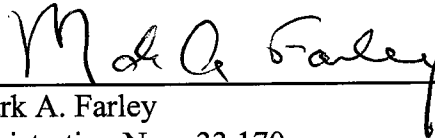
In support of the above conclusion, the declarant in ¶18 has cited the Examiner to paragraph [0011] of the Kropf reference which teaches that it is crucial that the active components be released from the support over a relatively long period and that the support material, i.e., an adhesive film, should not dissolve too rapidly in the mouth. It is well known that the coating upon a chewing gum base dissolves rapidly, primarily due to the fact that the coating is mainly formed of sugars or sugar alcohols. The Kropf reference thus teaches away from including the active components, i.e., calcium salt or calcium salt/protein composites, in the coating of a chewing gum.

Along the same lines, as discussed in declaration ¶19, the Greenberg reference, at col. 4, lines 48-51, states that the water-soluble portion, i.e., the coating, of the gum, dissipates with a portion of the flavor over a period of time while the gum is chewed, after which only the gum base portion is retained in the subject's mouth. Taking this teaching, as well, into account, applicants respectfully submit that, as noted in the indicated portion of the declaration one such as Dr. Kowalczyk having at least an ordinary level of skill in this field of art would not have considered that including the calcium salt composites described in Kropf into the chewing gum coating (as described in Greenberg) would, firstly, produce an acceptable chewing gum coating and, secondly, would have produced a beneficial effect upon the teeth on a subject who chewed such gum.

Based on the remarks provided above, and as supported by the evidentiary declaration under 37 C.F.R. §1.132 of Dr. Kowalczyk submitted herewith, applicants submit that the claims of their declaration are not be 'obvious' over the combined disclosure of Kropf and Greenberg. The Examiner is, thus, respectfully requested to reconsider and withdraw the rejection of the subject claims under 35 U.S.C. §103.

THIS CORRESPONDENCE IS BEING  
SUBMITTED ELECTRONICALLY  
THROUGH THE PATENT AND  
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Respectfully submitted,

A handwritten signature in cursive script, reading "Mark A. Farley", is written over a horizontal line.

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